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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,976	11/05/2001	Milton B. Yatvin	99,297	7958

20306 7590 10/02/2003

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,976	YATVIN ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 21, 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on July 21, 2003 in Paper No. 10 wherein claims 12-17 and 20-33 are cancelled.

Currently, claims 1-11 and 18-19 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7-9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatvin et al. (US 5,149,794) for reasons of record stated in the Office Action dated April 23, 2003.

Applicant's remarks filed on July 21, 2003 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant asserts that Yatvin et al. (US 5,149,794) uses only lipids attached to a drug for site specific drug delivery. Contrary to Applicant's assertion, as discussed in the previous Office Action, Yatvin (US 5,149,794) discloses a pharmaceutical composition comprising an antiviral or an anti proliferative or antineoplastic drug, a polar lipid carrier, and two linker functional groups and a spacer, wherein the spacer has a first end and a

second end and wherein the amino acid or amino acid derivative i.e., tBc-NHAla-Ala- or -Gly-Gly-Gly-Gly-NH-, is attached to the first of the spacer through a first linker functional group and the drug is attached to the second end of the spacer through a second linker functional group (see particularly Fig.1-8; Examples 1-8; claims 1 and 7). Moreover, Yatvin clearly discloses that the instant spacer is a peptide for (amino acid)n formula, a polymer of a particular amino acid (see claim 6 in particular) i.e., tBc-NHAla-Ala- or -Gly-Gly-Gly-Gly-NH-.

Thus, Yatvin et al. anticipates Claims 1, 3-5, 7-9 and 18.

Claims 1-5, 7-9, 11 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatvin et al. (US 5,543,389) for reasons of record stated in the Office Action dated April 23, 2003.

Applicant's remarks filed on July 21, 2003 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant asserts that Yatvin et al. (US 5,543,389) uses only lipids attached to a drug for site specific drug delivery. Contrary to Applicant's assertion, Yatvin (US 5,543,389) discloses a pharmaceutical composition comprising an antiviral or an anti proliferative or antineoplastic drug, a polar lipid carrier, and two linker functional groups and a spacer, wherein the spacer has a first end and a second end and wherein the amino acid or amino acid derivative is attached to the first of the spacer through a first

linker functional group and the drug is attached to the second end of the spacer through a second linker functional group (see particularly Fig.1; Example 1; claims 1-24); in particular Yatvin clearly discloses that the instant spacer is a peptide for (amino acid)n formula, a polymer of a particular amino acid (see claim 13) as discussed in the previous Office Action.

Thus, Yatvin et al. anticipates Claims 1-5, 7-9, 11 and 18-19.

Claims 1-5, 7-9, 11 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatvin et al. (US 5,827,819) for reasons of record stated in the Office Action dated April 23, 2003.

Applicant's remarks filed on July 21, 2003 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant asserts that Yatvin et al. (US 5,827,819) uses only lipids attached to a drug for site specific drug delivery. Contrary to Applicant's assertion, Yatvin (US 5,827,819) discloses a pharmaceutical composition comprising an antiviral or an anti proliferative or antineoplastic drug, a polar lipid carrier, and two linker functional groups and a spacer, wherein the spacer has a first end and a second end and wherein the amino acid or amino acid derivative is attached to the first of the spacer through a first linker functional group and the drug is attached to the second end of the spacer through a second linker functional group (see particularly Fig.1-6; Example 1-6; claims 1-12); in

particular Yatvin clearly discloses that the instant spacer is a peptide for (amino acid)n formula, a polymer of a particular amino acid (see claim 12) as discussed in the previous Office Action.

Thus, Yatvin et al. anticipates Claims 1-5, 7-9, 11 and 18-19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the same reference by Yatvin et al. (US 5,149,794) for reasons of record stated in the Office Action dated April 23, 2003.

Applicant's remarks filed on July 21, 2003 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Again, Applicant asserts that Yatvin et al. (US 5,149,794) uses only lipids attached to a drug for site specific drug delivery. As discussed above, Yatvin (US 5,149,794) clearly discloses that the instant spacer is a peptide for (amino acid)n formula, a polymer of a particular amino acid (see claim 6 in particular) i.e., tBc-NHAla-

Ala- or -Gly-Gly-Gly-Gly-NH-. Further, as discussed in the previous Office Action, therefore, one of ordinary skill in the art would have found it obvious to employ the particular known amino acid or derivative herein having the same or similar functional in the compositions of Yatvin et al.

Further, the record contains no clear and convincing evidence of unexpected results for the claimed invention herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-9 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,149,794 for reasons of record stated in the Office Action dated April 23, 2003.

Claims 1-5, 7-9, 11 and 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,543,389 for reasons of record stated in the Office Action dated April 23, 2003.

Claims 1-5, 7-9, 11 and 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,827,819.

Applicant's remarks filed on July 21, 2003 in Paper No. 10 with respect to these three obviousness-type double patenting rejections of record in the previous Office Action have been fully considered but are not deemed persuasive. These remarks are believed to be adequately addressed by the three rejections under 35 U.S.C. 102(b) as being anticipated by the same patents of Yatvin et al. above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
September 24, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER 9/28/03